

To whom it may concern

June 13, 2022

Statement – MRI Compatibility Enteral Feeding Products

We, **Fresenius Kabi AG**, as the legal manufacturer of the medical devices listed below, hereby confirm the following information concerning MRI Compatibility for these products:

a) MR safe:

product does not contain a metallic compound (guide wires of feeding tubes are made of stainless steel, but these guide wires are removed directly after the feeding tubes has been placed at its correct position, therefore this components are not considered here)

Article Code	Article Name	comment
7751541	Freka® Fixation Plate for Freka® PEG FR 20	MR safe
7751701	Freka® Tube Clamp for Freka® PEG FR 9/15	MR safe
7755695	Freka® Universal Funnel Adaptor, ENFit	MR safe
7903002	Freka® Fixation Plate for Freka® PEG FR 9	MR safe
7904002	Freka® Fixation Plate for Freka® PEG FR 15	MR safe
7981365	Freka® Adaptor LL-ENFit	MR safe
7981366	Freka® Connect Adaptor ENFit-LL	MR safe
7981367	Insert for Freka® GastroTube FR 15, ENFit	MR safe
7981376	Freka® ENFit/ENLock step adaptor	MR safe
7981377	Freka® MediAdaptor ENFit-LL	MR safe
7981383	Freka® Repair Set PEG FR 15, ENFit	MR safe
7981384	Freka® Repair Set PEG FR 20, ENFit	MR safe
7981386	Freka® Connector for Freka PEG FR 15, ENFit	MR safe
7981387	Freka® Connector for Freka PEG FR 20, ENFit	MR safe
7981394	Freka® Y-Connector for Freka® PEG FR 15/9, ENFit	MR safe
7981396	Freka® Y-Connector for Freka® PEG FR 20/12, ENFit	MR safe
7981403	Freka® Cap ENFit/ProNeo (1x30)	MR safe
7981907	Freka® Tape for tube fixation	MR safe
7981908	ProNeo Plaster	MR safe

Article Code	Article Name	comment
7755643	Freka® PEG CH/FR15, ENFit	MR safe
7755644	Freka® PEG CH/FR20, ENFit	MR safe
7981395	Freka® Y-Connector for Freka® PEG FR 20/9, ENFit	MR safe
7981941	Erlanger Dressing Set	MR safe
7981397	Freka® Button Extension set 1, right angled, ENFit	MR safe
7981398	Freka® Button Extension set 2, straight, ENFit	MR safe
7751562	Freka® Cone Adaptor, ENFit	MR safe
7751715T	Amika Pump Set Bag, universal, ENFit	MR safe
7751857	Applix VarioLine Adaptor, ENPlus	MR safe
7751900	Amika EasyBag, ENFit	MR safe
7751902	Amika Varioline, ENFit	MR safe
7751903	Amika TwoLine EasyBag, ENFit	MR safe
7751904	Amika Varioline Comfort, ENFit	MR safe
7751905	Amika EasyBag mobile, ENFit	MR safe
7751906	Amika Bag mobile, ENFit	MR safe
7751907	Amika Pump Set EasyBag, universal, ENFit	MR safe
7751908	Amika Pump Set Bag, universal, ENFit	MR safe
7751909	Amika Pump Set Varioline, universal, ENFit	MR safe
7751910	Amika Pump Set TwoLine Easybag, universal, ENFit	MR safe
7751913	Amika Pump Set Bag mobile, universal, ENFit	MR safe
7751914	Amika Bag with cover, ENFit	MR safe
7751915	Amika Bag mobile with cover, ENFit	MR safe
7751916	Amika EasyBag mobile with cover, ENFit	MR safe
7751917	Amika EasyBag with cover, ENFit	MR safe
7751918	Amika EasyBag non med port with cover, ENFit	MR safe
7751919	Amika Varioline with cover, ENFit	MR safe
7751923	Applix Smart/Vision Bag, ENFit	MR safe
7751924	Applix Smart/Vision Varioline, ENFit	MR safe
7751925	Applix Smart/Vision TwoLine EasyBag, ENFit	MR safe
7751926	Applix Smart/Vision Varioline Comfort, ENFit	MR safe
7751927	Applix Smart/Vision EasyBag mobile, ENFit	MR safe
7751928	Applix Smart/Vision Bag mobile, ENFit	MR safe
7751929	Applix Smart/Vision EasyBag with cover, ENFit	MR safe
7751930	Applix Smart/Vision EasyBag non med port with cover, ENFit	MR safe
7751932	Applix Smart/Vision Varioline with cover, ENFit	MR safe

Article Code	Article Name	comment
7751933	Applix Smart/Vision Bag with cover, ENFit	MR safe
7751934	Applix Smart/Vision Bag mobile with cover, ENFit	MR safe
7751935	Applix Smart/Vision TwoLine EasyBag with cover, ENFit	MR safe
7751936	GraviSet EasyBag, ENFit	MR safe
7751937	GraviSet Varioline, ENFit	MR safe
7751938	GraviSet Bag, ENFit	MR safe
7751939	GraviSet EasyBag with cover, ENFit	MR safe
7751943	Applix Smart/Vision Pump Set EasyBag, universal, ENFit	MR safe
7751944	Applix Smart/Vision Pump Set EasyBag with cover, universal, ENFit	MR safe
7751945	Applix Smart/Vision Pump Set Bag, universal, ENFit	MR safe
7751946	Applix Smart/Vision Pump Set Varioline, universal, ENFit	MR safe
7751947	Applix Smart/Vision Pump Set TwoLine EasyBag, universal, ENFit	MR safe
7751948	Applix Smart/Vision Pump Set Varioline Comfort, universal, ENFit	MR safe
7751949	Applix Smart/Vision Pump Set EasyBag mobile, universal, ENFit	MR safe
7751950	Applix Smart/Vision Pump Set Bag mobile, universal, ENFit	MR safe
7751952	GraviSet EasyBag, universal, ENFit	MR safe
7751953	GraviSet Varioline, universal, ENFit	MR safe
7751954	GraviSet Bag, universal, ENFit	MR safe
7751955	GraviSet EasyBag with cover, universal, ENFit	MR safe
7751956	Amika Bag, ENFit	MR safe
7751994	Amika TwoLine EasyBag with cover, ENFit	MR safe
7751995	Applix Smart/Vision EasyBag, ENFit	MR safe
7751996	Applix Smart/Vision EasyBag mobile with cover, ENFit	MR safe
7751998	Amika Pump Set Varioline Comfort, universal, ENFit	MR safe
7751999	Amika Pump Set EasyBag mobile, universal, ENFit	MR safe
7752085T	Amika Pump Set EasyBag, universal, ENFit	MR safe
7755692	ENContainer adaptor	MR safe
7755693	Giving Set Extension 100 cm, ENFit	MR safe
7755694	EasyBag Bolus Adaptor, ENFit	MR safe
7981838	Freka® Dual Port Connection, ENFit	MR safe
7989923	Easy Bottle Adaptor Gravity, ENPlus	MR safe
7752002	ProNeo Multifunction Syringe Cap	MR safe

Article Code	Article Name	comment
7752003	ProNeo MilkBottle Adapter	MR safe
7752004	ProNeo Medication Adapter	MR safe
7752005	ProNeo Extension, 120 cm	MR safe
7752006	ProNeo Extension, 30 cm	MR safe
7752007	ProNeo Feeding Tube FR 8, 60 cm	MR safe
7752008	ProNeo Feeding Tube FR 6, 50 cm	MR safe
7752009	ProNeo Feeding Tube FR 5, 50 cm	MR safe
7752010	ProNeo Feeding Tube FR 4, 40 cm	MR safe
7752022	ProNeo Feeding Tube FR 4, 50 cm	MR safe
7752023	ProNeo Feeding Tube FR 4, 70 cm	MR safe
7752024	ProNeo Feeding Tube FR 5, 40 cm	MR safe
7752026	ProNeo Feeding Tube FR 5, 70 cm	MR safe
7752027	ProNeo Feeding Tube FR 6, 40 cm	MR safe
7752028	ProNeo Feeding Tube FR 6, 70 cm	MR safe
7752029	ProNeo Feeding Tube FR 6, 120 cm	MR safe
7752030	ProNeo Feeding Tube FR 8, 50 cm	MR safe
7980951	Freka® Sil Tube FR 16, 100 cm, F	MR safe
7981826	Freka® Tube FR 8, 80cm, ENFit	MR safe
7981827	Freka® Tube FR 8, 120cm, ENFit	MR safe
7981828	Freka® Tube FR 10, 120cm, ENFit	MR safe
7981829	Freka® Tube FR 12, 120cm, ENFit	MR safe
7981830	Freka® Tube FR 15, 120cm, ENFit	MR safe
7981834	Freka® Trelumina, ENFit	MR safe
7981835	Freka® Sil FR 8, ENFit	MR safe
7981836	Freka® Sil FR 13, ENFit	MR safe
7981837	Freka® Sil FR 16, ENFit	MR safe
7981839	Freka® Tube FR 8 linear, 80 cm, ENFit	MR safe
7981840	Freka® Tube FR 8 linear, 120 cm, ENFit	MR safe
7981842	Freka® Tube FR 10 linear, 120 cm, ENFit	MR safe
7981843	Freka® Tube FR 12 linear, 120 cm, ENFit	MR safe
7981844	Freka® Tube FR 15 linear, 120 cm, ENFit	MR safe
7981845	Freka® Tube FR 10 linear, 80cm, ENFit	MR safe
7981402	Freka® Cap ENFit™/ProNeo	MR safe
9000782LDT	Freka® Connect ENFit/ProNeo LDT 2,5 ml (30x1)	MR safe
9000783LDT	Freka® Connect ENFit/ProNeo LDT 5 ml (30x1)	MR safe

Article Code	Article Name	comment
9000784	Freka® Connect ENFit/ProNeo 10 ml (100x1)	MR safe
9000784S	Freka® Connect ENFit/ProNeo 10 ml (30x1)	MR safe
9000784XS	Freka® Connect ENFit/ProNeo 10 ml (10x1)	MR safe
9000785	Freka® Connect ENFit/ProNeo 20 ml (100x1)	MR safe
9000785S	Freka® Connect ENFit/ProNeo 20 ml (30x1)	MR safe
9000785XS	Freka® Connect ENFit/ProNeo 20 ml (10x1)	MR safe
9000786	Freka® Connect ENFit/ProNeo 60 ml (50x1)	MR safe
9000786S	Freka® Connect ENFit/ProNeo 60 ml (30x1)	MR safe
9000786XS	Freka® Connect ENFit/ProNeo 60 ml (10x1)	MR safe
9000787	Freka® Connect ENFit/ProNeo 100 ml (30x1)	MR safe
9000787XS	Freka® Connect ENFit/ProNeo 100 ml (10x1)	MR safe
9000788LDT	Freka® Connect ENFit/ProNeo LDT 1 ml (30x1)	MR safe
9000789	Freka® Connect ENFit / ProNeo, 60ml eccentric	MR safe

b) MR conditional:

product does contain a metallic compound therefore special conditions apply if patient needs to have an MRI scan

Article Code	Article Name	comment
7981382	Freka® Repair Set PEG FR 9, ENFit	MR conditional
M90800400	Repair Set Freka® PEG Pro, FR 12	MR conditional
7981385	Freka® Connector for Freka PEG FR 9, ENFit	MR conditional
M90800490	Connector Freka® PEG Pro FR 12, ENFit	MR conditional
7981388	Freka® Repair Set for Freka® FCJ, ENFit	MR conditional
7981389	Freka® Click Adaptor FR 9 for PEG FR 15, ENFit	MR conditional
7981390	Freka® Click Adaptor FR 12 for PEG FR 20, ENFit	MR conditional
7755642	Freka® PEG CH/FR9, ENFit	MR conditional
M90800346	Freka® PEG Pro Set FR 12	MR conditional
7755645	Freka® FCJ FR 9, ENFit	MR conditional
7755646	Freka® Intestinal Tube FR 9 for Freka® PEG FR 15, ENFit	MR conditional
7755647	Freka® Intestinal Tube FR 12 for Freka® PEG FR 20, ENFit	MR conditional
7751241	Freka® Button FR 15, 1.1 cm	MR conditional
7751251	Freka® Button FR 15, 1.4 cm	MR conditional

Article Code	Article Name	comment
7751261	Freka® Button FR 15, 1.7 cm	MR conditional
7751271	Freka® Button FR 15, 2.0 cm	MR conditional
7751281	Freka® Button FR 15, 2.5 cm	MR conditional
7751291	Freka® Button FR 15, 3.0 cm	MR conditional
7751301	Freka® Button FR 15, 3.5 cm	MR conditional
7751311	Freka® Button FR 15, 4.0 cm	MR conditional
7751321	Freka® Button FR 15, 4.5 cm	MR conditional
7751363	Freka® Belly Button, Comfort Kit, FR 12 1.0 cm, ENFit	MR conditional
7751364	Freka® Belly Button, Comfort Kit, FR 12 1.5 cm, ENFit	MR conditional
7751365	Freka® Belly Button, Comfort Kit, FR 12 2.0 cm, ENFit	MR conditional
7751366	Freka® Belly Button, Comfort Kit, FR 12 2.5 cm, ENFit	MR conditional
7751367	Freka® Belly Button, Comfort Kit, FR 12 3.0 cm, ENFit	MR conditional
7751368	Freka® Belly Button, Comfort Kit, FR 12 3.5 cm, ENFit	MR conditional
7751369	Freka® Belly Button, Comfort Kit, FR 12 4.0 cm, ENFit	MR conditional
7751370	Freka® Belly Button, Comfort Kit, FR 12 4.5 cm, ENFit	MR conditional
7751372	Freka® Belly Button, Comfort Kit, FR 12 5.0 cm, ENFit	MR conditional
7751373	Freka® Belly Button, Comfort Kit, FR 14 1.0 cm, ENFit	MR conditional
7751374	Freka® Belly Button, Comfort Kit, FR 14 1.5 cm, ENFit	MR conditional
7751375	Freka® Belly Button, Comfort Kit, FR 14 2.0 cm, ENFit	MR conditional
7751376	Freka® Belly Button, Comfort Kit, FR 14 2.5 cm, ENFit	MR conditional
7751377	Freka® Belly Button, Comfort Kit, FR 14 3.0 cm, ENFit	MR conditional
7751378	Freka® Belly Button, Comfort Kit, FR 14 3.5 cm, ENFit	MR conditional
7751379	Freka® Belly Button, Comfort Kit, FR 14 4.0 cm, ENFit	MR conditional
7751380	Freka® Belly Button, Comfort Kit, FR 14 4.5 cm, ENFit	MR conditional
7751382	Freka® Belly Button, Comfort Kit, FR 14 5.0 cm, ENFit	MR conditional
7751383	Freka® Belly Button, Comfort Kit, FR 16 1.0 cm, ENFit	MR conditional
7751384	Freka® Belly Button, Comfort Kit, FR 16 1.5 cm, ENFit	MR conditional
7751385	Freka® Belly Button, Comfort Kit, FR 16 2.0 cm, ENFit	MR conditional
7751386	Freka® Belly Button, Comfort Kit, FR 16 2.5 cm, ENFit	MR conditional
7751387	Freka® Belly Button, Comfort Kit, FR 16 3.0 cm, ENFit	MR conditional
7751388	Freka® Belly Button, Comfort Kit, FR 16 3.5 cm, ENFit	MR conditional
7751389	Freka® Belly Button, Comfort Kit, FR 16 4.0 cm, ENFit	MR conditional
7751390	Freka® Belly Button, Comfort Kit, FR 16 4.5 cm, ENFit	MR conditional
7751393	Freka® Belly Button, Comfort Kit, FR 16 5.0 cm, ENFit	MR conditional
7751394	Freka® Belly Button, Comfort Kit, FR 18 1.0 cm, ENFit	MR conditional

Article Code	Article Name	comment
7751395	Freka® Belly Button, Comfort Kit, FR 18 1.5 cm, ENFit	MR conditional
7751396	Freka® Belly Button, Comfort Kit, FR 18 2.0 cm, ENFit	MR conditional
7751397	Freka® Belly Button, Comfort Kit, FR 18 2.5 cm, ENFit	MR conditional
7751398	Freka® Belly Button, Comfort Kit, FR 18 3.0 cm, ENFit	MR conditional
7751399	Freka® Belly Button, Comfort Kit, FR 18 3.5 cm, ENFit	MR conditional
7751400	Freka® Belly Button, Comfort Kit, FR 18 4.0 cm, ENFit	MR conditional
7751403	Freka® Belly Button, Comfort Kit, FR 18 4.5 cm, ENFit	MR conditional
7751404	Freka® Belly Button, Comfort Kit, FR 18 5.0 cm, ENFit	MR conditional
7751405	Freka® Belly Button, Comfort Kit, FR 20 1.0 cm, ENFit	MR conditional
7751406	Freka® Belly Button, Comfort Kit, FR 20 1.5 cm, ENFit	MR conditional
7751407	Freka® Belly Button, Comfort Kit, FR 20 2.0 cm, ENFit	MR conditional
7751408	Freka® Belly Button, Comfort Kit, FR 20 2.5 cm, ENFit	MR conditional
7751409	Freka® Belly Button, Comfort Kit, FR 20 3.0 cm, ENFit	MR conditional
7751410	Freka® Belly Button, Comfort Kit, FR 20 3.5 cm, ENFit	MR conditional
7751413	Freka® Belly Button, Comfort Kit, FR 20 4.0 cm, ENFit	MR conditional
7751414	Freka® Belly Button, Comfort Kit, FR 20 4.5 cm, ENFit	MR conditional
7751415	Freka® Belly Button, Comfort Kit, FR 20 5.0 cm, ENFit	MR conditional
7751416	Freka® Belly Button, Comfort Kit, FR 24 1.0 cm, ENFit	MR conditional
7751417	Freka® Belly Button, Comfort Kit, FR 24 1.5 cm, ENFit	MR conditional
7751418	Freka® Belly Button, Comfort Kit, FR 24 2.0 cm, ENFit	MR conditional
7751419	Freka® Belly Button, Comfort Kit, FR 24 2.5 cm, ENFit	MR conditional
7751420	Freka® Belly Button, Comfort Kit, FR 24 3.0 cm, ENFit	MR conditional
7751422	Freka® Belly Button, Comfort Kit, FR 24 3.5 cm, ENFit	MR conditional
7751423	Freka® Belly Button, Comfort Kit, FR 24 4.0 cm, ENFit	MR conditional
7751424	Freka® Belly Button, Comfort Kit, FR 24 4.5 cm, ENFit	MR conditional
7751425	Freka® Belly Button, Comfort Kit, FR 24 5.0 cm, ENFit	MR conditional
7751612	Freka® Belly Button Basic, FR 12, 1.0 cm	MR conditional
7751613	Freka® Belly Button Basic, FR 12, 1.5 cm	MR conditional
7751614	Freka® Belly Button Basic, FR 12, 2.0 cm	MR conditional
7751615	Freka® Belly Button Basic, FR 12, 2.5 cm	MR conditional
7751616	Freka® Belly Button Basic, FR 12, 3.0 cm	MR conditional
7751617	Freka® Belly Button Basic, FR 12, 3.5 cm	MR conditional
7751618	Freka® Belly Button Basic, FR 12, 4.0 cm	MR conditional
7751619	Freka® Belly Button Basic, FR 12, 4.5 cm	MR conditional
7751620	Freka® Belly Button Basic, FR 12, 5.0 cm	MR conditional

Article Code	Article Name	comment
7751622	Freka® Belly Button Basic, FR 14, 1.0 cm	MR conditional
7751623	Freka® Belly Button Basic, FR 14, 1.5 cm	MR conditional
7751624	Freka® Belly Button Basic, FR 14, 2.0 cm	MR conditional
7751625	Freka® Belly Button Basic, FR 14, 2.5 cm	MR conditional
7751626	Freka® Belly Button Basic, FR 14, 3.0 cm	MR conditional
7751627	Freka® Belly Button Basic, FR 14, 3.5 cm	MR conditional
7751628	Freka® Belly Button Basic, FR 14, 4.0 cm	MR conditional
7751629	Freka® Belly Button Basic, FR 14, 4.5 cm	MR conditional
7751630	Freka® Belly Button Basic, FR 14, 5.0 cm	MR conditional
7751632	Freka® Belly Button Basic, FR 16, 1.0 cm	MR conditional
7751633	Freka® Belly Button Basic, FR 16, 1.5 cm	MR conditional
7751634	Freka® Belly Button Basic, FR 16, 2.0 cm	MR conditional
7751635	Freka® Belly Button Basic, FR 16, 2.5 cm	MR conditional
7751636	Freka® Belly Button Basic, FR 16, 3.0 cm	MR conditional
7751637	Freka® Belly Button Basic, FR 16, 3.5 cm	MR conditional
7751638	Freka® Belly Button Basic, FR 16, 4.0 cm	MR conditional
7751639	Freka® Belly Button Basic, FR 16, 4.5 cm	MR conditional
7751640	Freka® Belly Button Basic, FR 16, 5.0 cm	MR conditional
7751642	Freka® Belly Button Basic, FR 18, 1.0 cm	MR conditional
7751643	Freka® Belly Button Basic, FR 18, 1.5 cm	MR conditional
7751644	Freka® Belly Button Basic, FR 18, 2.0 cm	MR conditional
7751645	Freka® Belly Button Basic, FR 18, 2.5 cm	MR conditional
7751646	Freka® Belly Button Basic, FR 18, 3.0 cm	MR conditional
7751647	Freka® Belly Button Basic, FR 18, 3.5 cm	MR conditional
7751648	Freka® Belly Button Basic, FR 18, 4.0 cm	MR conditional
7751649	Freka® Belly Button Basic, FR 18, 4.5 cm	MR conditional
7751650	Freka® Belly Button Basic, FR 18, 5.0 cm	MR conditional
7751652	Freka® Belly Button Basic, FR 20, 1.0 cm	MR conditional
7751653	Freka® Belly Button Basic, FR 20, 1.5 cm	MR conditional
7751654	Freka® Belly Button Basic, FR 20, 2.0 cm	MR conditional
7751655	Freka® Belly Button Basic, FR 20, 2.5 cm	MR conditional
7751656	Freka® Belly Button Basic, FR 20, 3.0 cm	MR conditional
7751657	Freka® Belly Button Basic, FR 20, 3.5 cm	MR conditional
7751658	Freka® Belly Button Basic, FR 20, 4.0 cm	MR conditional
7751659	Freka® Belly Button Basic, FR 20, 4.5 cm	MR conditional

Article Code	Article Name	comment
7751660	Freka® Belly Button Basic, FR 20, 5.0 cm	MR conditional
7751662	Freka® Belly Button Basic, FR 24, 1.0 cm	MR conditional
7751663	Freka® Belly Button Basic, FR 24, 1.5 cm	MR conditional
7751664	Freka® Belly Button Basic, FR 24, 2.0 cm	MR conditional
7751665	Freka® Belly Button Basic, FR 24, 2.5 cm	MR conditional
7751666	Freka® Belly Button Basic, FR 24, 3.0 cm	MR conditional
7751667	Freka® Belly Button Basic, FR 24, 3.5 cm	MR conditional
7751668	Freka® Belly Button Basic, FR 24, 4.0 cm	MR conditional
7751669	Freka® Belly Button Basic, FR 24, 4.5 cm	MR conditional
7751670	Freka® Belly Button Basic, FR 24, 5.0 cm	MR conditional
7755648	Freka® GastroTube FR15, ENFit	MR conditional
7981832	Freka® Endolumina, ENFit	MR conditional
7981833	Freka® EasyIn, ENFit	MR conditional

c) not applicable (n/a):

product does contain a metal component but is not used at the patient while patient is in the MRI

Article Code	Article Name	comment
7750921	Freka® Stoma Measuring Device	n/a
7989911	Freka® Seldinger Wire, 80 cm	n/a
7980321	Freka® Endo-Mandrin, 300 cm	n/a

d) MRI test not yet performed

to be clarified during MDR TF update whether test would be needed

Article Code	Article Name	comment
7901081	Hermann Gastrostomy Dressing Set	-

For products which are MR conditional, the following **MRI safety information** applies.

Article Code	Article Name
7755642	Freka® PEG CH/FR9, ENFit
7755645	Freka® FCJ FR 9, ENFit
7981832	Freka® Endolumina, ENFit
7981833	Freka® EasyIn, ENFit
7981382	Freka® Repair Set PEG FR 9, ENFit
7981385	Freka® Connector for Freka PEG FR 9, ENFit
7981388	Freka® Repair Set for Freka® FCJ, ENFit
7981389	Freka® Click Adaptor FR 9 for PEG FR 15, ENFit
7981390	Freka® Click Adaptor FR 12 for PEG FR 20, ENFit

MR Conditional

Non-clinical testing has demonstrated the **[product as given in table above]** is MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of **3** Tesla or less, with
- Maximum spatial field gradient of **800** G/cm (8 T/m)
- Maximum force product of **14** T²/m
- Theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of
2 W/kg (Normal Operating Mode) or
4 W/kg (First Level Controlled Operating Mode)

Non-clinical testing of RF-heating of the **[product as given in table above]** has not been performed, due to embedding in plastic insulator material and small size compared to half wavelength within tissue of the electrically conductive component. Therefore, no significant heating due to RF interactions is expected.

In non-clinical testing, the image artifact caused by the device extends approximately **47.4** mm from the **[product as given in table above]** when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.

Article Code	Article Name
M90800346	Freka® PEG Pro Set FR 12
M90800400	Repair Set Freka® PEG Pro, FR 12
M90800490	Connector Freka® PEG Pro FR 12, ENFit

MR Conditional

Non-clinical testing has demonstrated the **[product as given in table above]** is MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of **3** Tesla or less, with
- Maximum spatial field gradient of **7.300** G/cm (73 T/m)
- Maximum force product of **131** T²/m
- Theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of

2 W/kg (Normal Operating Mode) or

4 W/kg (First Level Controlled Operating Mode)

Non-clinical testing of RF-heating of the **[product as given in table above]** has not been performed, due to embedding in plastic insulator material and small size compared to half wavelength within tissue of the electrically conductive component. Therefore, no significant heating due to RF interactions is expected.

In non-clinical testing, the image artifact caused by the device extends approximately **39.7** mm from the **[product as given in table above]** when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.

Article Code	Article Name
7755646	Freka® Intestinal Tube FR 9 for Freka® PEG FR 15, ENFit
7755647	Freka® Intestinal Tube FR 12 for Freka® PEG FR 20, ENFit

MR Conditional

Non-clinical testing has demonstrated the **[product as given in table above]** is MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of **3** Tesla or less, with
- Maximum spatial field gradient of **190** G/cm (1.9 T/m)
- Maximum force product of **3.5** T²/m
- Theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of
2 W/kg (Normal Operating Mode) or
4 W/kg (First Level Controlled Operating Mode)

Non-clinical testing of RF-heating of the **[product as given in table above]** has not been performed, due to embedding in plastic insulator material and small size compared to half wavelength within tissue of the electrically conductive component. Therefore, no significant heating due to RF interactions is expected.

In non-clinical testing, the image artifact caused by the device extends approximately **55.8** mm from the **[product as given in table above]** when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.

Article Code	Article Name
7755648	Freka® GastroTube FR15, ENFit
7751241	Freka® Button FR 15, 1.1 cm
7751251	Freka® Button FR 15, 1.4 cm
7751261	Freka® Button FR 15, 1.7 cm
7751271	Freka® Button FR 15, 2.0 cm
7751281	Freka® Button FR 15, 2.5 cm
7751291	Freka® Button FR 15, 3.0 cm
7751301	Freka® Button FR 15, 3.5 cm
7751311	Freka® Button FR 15, 4.0 cm
7751321	Freka® Button FR 15, 4.5 cm

MR Conditional

Non-clinical testing has demonstrated the **[product as given in table above]** is MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of **3** Tesla or less, with
- Maximum spatial field gradient of **12,800** G/cm (128 T/m)
- Maximum force product of **231,000,000** G²/cm (231 T²/m)
- Theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of

2 W/kg (Normal Operating Mode) or

4 W/kg (First Level Controlled Operating Mode)

Non-clinical testing of RF-heating of the **[product as given in table above]** has not been performed, due to embedding in plastic insulator material and small size compared to half wavelength within tissue of the electrically conductive component. Therefore, no significant heating due to RF interactions is expected.

In non-clinical testing, the image artifact caused by the device extends approximately **7.38** mm from the **[product as given in table above]** when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.

Article Code	Article Name	Article Code	Article Name
7751363	Freka® Belly Button, Comfort Kit, FR 12 1.0 cm, ENFit	7751373	Freka® Belly Button, Comfort Kit, FR 14 1.0 cm, ENFit
7751364	Freka® Belly Button, Comfort Kit, FR 12 1.5 cm, ENFit	7751374	Freka® Belly Button, Comfort Kit, FR 14 1.5 cm, ENFit
7751365	Freka® Belly Button, Comfort Kit, FR 12 2.0 cm, ENFit	7751375	Freka® Belly Button, Comfort Kit, FR 14 2.0 cm, ENFit
7751366	Freka® Belly Button, Comfort Kit, FR 12 2.5 cm, ENFit	7751376	Freka® Belly Button, Comfort Kit, FR 14 2.5 cm, ENFit
7751367	Freka® Belly Button, Comfort Kit, FR 12 3.0 cm, ENFit	7751377	Freka® Belly Button, Comfort Kit, FR 14 3.0 cm, ENFit
7751368	Freka® Belly Button, Comfort Kit, FR 12 3.5 cm, ENFit	7751378	Freka® Belly Button, Comfort Kit, FR 14 3.5 cm, ENFit
7751369	Freka® Belly Button, Comfort Kit, FR 12 4.0 cm, ENFit	7751379	Freka® Belly Button, Comfort Kit, FR 14 4.0 cm, ENFit
7751370	Freka® Belly Button, Comfort Kit, FR 12 4.5 cm, ENFit	7751380	Freka® Belly Button, Comfort Kit, FR 14 4.5 cm, ENFit
7751372	Freka® Belly Button, Comfort Kit, FR 12 5.0 cm, ENFit	7751382	Freka® Belly Button, Comfort Kit, FR 14 5.0 cm, ENFit
7751383	Freka® Belly Button, Comfort Kit, FR 16 1.0 cm, ENFit	7751394	Freka® Belly Button, Comfort Kit, FR 18 1.0 cm, ENFit
7751384	Freka® Belly Button, Comfort Kit, FR 16 1.5 cm, ENFit	7751395	Freka® Belly Button, Comfort Kit, FR 18 1.5 cm, ENFit
7751385	Freka® Belly Button, Comfort Kit, FR 16 2.0 cm, ENFit	7751396	Freka® Belly Button, Comfort Kit, FR 18 2.0 cm, ENFit
7751386	Freka® Belly Button, Comfort Kit, FR 16 2.5 cm, ENFit	7751397	Freka® Belly Button, Comfort Kit, FR 18 2.5 cm, ENFit
7751387	Freka® Belly Button, Comfort Kit, FR 16 3.0 cm, ENFit	7751398	Freka® Belly Button, Comfort Kit, FR 18 3.0 cm, ENFit
7751388	Freka® Belly Button, Comfort Kit, FR 16 3.5 cm, ENFit	7751399	Freka® Belly Button, Comfort Kit, FR 18 3.5 cm, ENFit
7751389	Freka® Belly Button, Comfort Kit, FR 16 4.0 cm, ENFit	7751400	Freka® Belly Button, Comfort Kit, FR 18 4.0 cm, ENFit
7751390	Freka® Belly Button, Comfort Kit, FR 16 4.5 cm, ENFit	7751403	Freka® Belly Button, Comfort Kit, FR 18 4.5 cm, ENFit
7751393	Freka® Belly Button, Comfort Kit, FR 16 5.0 cm, ENFit	7751404	Freka® Belly Button, Comfort Kit, FR 18 5.0 cm, ENFit
7751405	Freka® Belly Button, Comfort Kit, FR 20 1.0 cm, ENFit	7751416	Freka® Belly Button, Comfort Kit, FR 24 1.0 cm, ENFit
7751406	Freka® Belly Button, Comfort Kit, FR 20 1.5 cm, ENFit	7751417	Freka® Belly Button, Comfort Kit, FR 24 1.5 cm, ENFit
7751407	Freka® Belly Button, Comfort Kit, FR 20 2.0 cm, ENFit	7751418	Freka® Belly Button, Comfort Kit, FR 24 2.0 cm, ENFit
7751408	Freka® Belly Button, Comfort Kit, FR 20 2.5 cm, ENFit	7751419	Freka® Belly Button, Comfort Kit, FR 24 2.5 cm, ENFit
7751409	Freka® Belly Button, Comfort Kit, FR 20 3.0 cm, ENFit	7751420	Freka® Belly Button, Comfort Kit, FR 24 3.0 cm, ENFit
7751410	Freka® Belly Button, Comfort Kit, FR 20 3.5 cm, ENFit	7751422	Freka® Belly Button, Comfort Kit, FR 24 3.5 cm, ENFit
7751413	Freka® Belly Button, Comfort Kit, FR 20 4.0 cm, ENFit	7751423	Freka® Belly Button, Comfort Kit, FR 24 4.0 cm, ENFit
7751414	Freka® Belly Button, Comfort Kit, FR 20 4.5 cm, ENFit	7751424	Freka® Belly Button, Comfort Kit, FR 24 4.5 cm, ENFit
7751415	Freka® Belly Button, Comfort Kit, FR 20 5.0 cm, ENFit	7751425	Freka® Belly Button, Comfort Kit, FR 24 5.0 cm, ENFit
7751612	Freka® Belly Button Basic, FR 12, 1.0 cm	7751622	Freka® Belly Button Basic, FR 14, 1.0 cm
7751613	Freka® Belly Button Basic, FR 12, 1.5 cm	7751623	Freka® Belly Button Basic, FR 14, 1.5 cm
7751614	Freka® Belly Button Basic, FR 12, 2.0 cm	7751624	Freka® Belly Button Basic, FR 14, 2.0 cm
7751615	Freka® Belly Button Basic, FR 12, 2.5 cm	7751625	Freka® Belly Button Basic, FR 14, 2.5 cm

Article Code	Article Name	Article Code	Article Name
7751616	Freka® Belly Button Basic, FR 12, 3.0 cm	7751626	Freka® Belly Button Basic, FR 14, 3.0 cm
7751617	Freka® Belly Button Basic, FR 12, 3.5 cm	7751627	Freka® Belly Button Basic, FR 14, 3.5 cm
7751618	Freka® Belly Button Basic, FR 12, 4.0 cm	7751628	Freka® Belly Button Basic, FR 14, 4.0 cm
7751619	Freka® Belly Button Basic, FR 12, 4.5 cm	7751629	Freka® Belly Button Basic, FR 14, 4.5 cm
7751620	Freka® Belly Button Basic, FR 12, 5.0 cm	7751630	Freka® Belly Button Basic, FR 14, 5.0 cm
7751632	Freka® Belly Button Basic, FR 16, 1.0 cm	7751642	Freka® Belly Button Basic, FR 18, 1.0 cm
7751633	Freka® Belly Button Basic, FR 16, 1.5 cm	7751643	Freka® Belly Button Basic, FR 18, 1.5 cm
7751634	Freka® Belly Button Basic, FR 16, 2.0 cm	7751644	Freka® Belly Button Basic, FR 18, 2.0 cm
7751635	Freka® Belly Button Basic, FR 16, 2.5 cm	7751645	Freka® Belly Button Basic, FR 18, 2.5 cm
7751636	Freka® Belly Button Basic, FR 16, 3.0 cm	7751646	Freka® Belly Button Basic, FR 18, 3.0 cm
7751637	Freka® Belly Button Basic, FR 16, 3.5 cm	7751647	Freka® Belly Button Basic, FR 18, 3.5 cm
7751638	Freka® Belly Button Basic, FR 16, 4.0 cm	7751648	Freka® Belly Button Basic, FR 18, 4.0 cm
7751639	Freka® Belly Button Basic, FR 16, 4.5 cm	7751649	Freka® Belly Button Basic, FR 18, 4.5 cm
7751640	Freka® Belly Button Basic, FR 16, 5.0 cm	7751650	Freka® Belly Button Basic, FR 18, 5.0 cm
7751652	Freka® Belly Button Basic, FR 20, 1.0 cm	7751662	Freka® Belly Button Basic, FR 24, 1.0 cm
7751653	Freka® Belly Button Basic, FR 20, 1.5 cm	7751663	Freka® Belly Button Basic, FR 24, 1.5 cm
7751654	Freka® Belly Button Basic, FR 20, 2.0 cm	7751664	Freka® Belly Button Basic, FR 24, 2.0 cm
7751655	Freka® Belly Button Basic, FR 20, 2.5 cm	7751665	Freka® Belly Button Basic, FR 24, 2.5 cm
7751656	Freka® Belly Button Basic, FR 20, 3.0 cm	7751666	Freka® Belly Button Basic, FR 24, 3.0 cm
7751657	Freka® Belly Button Basic, FR 20, 3.5 cm	7751667	Freka® Belly Button Basic, FR 24, 3.5 cm
7751658	Freka® Belly Button Basic, FR 20, 4.0 cm	7751668	Freka® Belly Button Basic, FR 24, 4.0 cm
7751659	Freka® Belly Button Basic, FR 20, 4.5 cm	7751669	Freka® Belly Button Basic, FR 24, 4.5 cm
7751660	Freka® Belly Button Basic, FR 20, 5.0 cm	7751670	Freka® Belly Button Basic, FR 24, 5.0 cm

MR conditional

Non-clinical testing has demonstrated the **[product as given in table above]** is MR conditional.

A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of **1.5 T** and **3.0 T**
- Maximum spatial field gradient of **4.170 G/cm** (41 T/m)
- Maximum MR system reported, whole body averaged (WBA) specific absorption rate (SAR) of **<2 W/kg** (Normal Operating Mode)

Under the scan conditions defined above, the **[product as given in table above]** is expected to produce a maximum temperature rise of less than **0.4 °C** (2W/kg; 1.5T) and **0.9 °C** (2W/kg, 3T) after **15** minutes of continuous scanning.

Page 16/16

For and on behalf of Fresenius Kabi AG,

i.V. 

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