

Packaging

dimedada[®]
SURGICAL INSTRUMENTS

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Reusable surgical instruments

**Manufacturer according to Regulation (EU) 2017/745
MDR**

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Packaging

1 Packaging

There are several primary packaging options, which serve to protect or store the instruments.

- ✓ LD/PE film
- ✓ LD/PE bubble wrap
- ✓ Vinyl protective caps
- ✓ Precision protective cap made of thermoplastic elastomer (TPE)
- ✓ PVC or silicone as protective hose
- ✓ PUR flexible foam

Furthermore, the products are then adequately protected from damage by suitable secondary packaging.




- ✓ Packaging chips
- ✓ LD/PE bubble wrap
- ✓ Cardboard boxes
- ✓ Polystyrene cases




1.1 Primary packaging(s)

The instruments are packed in the following primary packaging.

Protective caps are attached to products with pointed components to protect them from transport damage or perforation. These are made of e.g. silicone, vinyl or PVC and are cut to size or are already available in the form of a protective cap. The packaging is widely used in medical technology and is considered state of the art for non-sterile instruments. Evidence of clinical safety has been sufficiently evaluated and approved in the biological assessment.

The following is a detailed list of the primary packaging used:

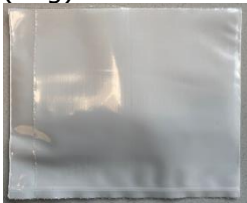

No.	Description	Data sheet	Evidence / location
1.	LD/PE film (bag) 	<ul style="list-style-type: none"> • Data sheet LDPE flat bags 	1.7.3 Specification packaging material
2.	Vinyl protective caps 	<ul style="list-style-type: none"> • 01050,01051,01052,01483_Tip guards_Specification_DE_EN • 01058 Data sheet • 	1.7.3 Specification packaging material
3.	Precision protective cap made of thermoplastic elastomer (TPE) 	<ul style="list-style-type: none"> • 30001 data sheet • 30003 data sheet • 30004 data sheet • 30005 data sheet • 30016 Data sheet 	1.7.3 Specification packaging material

4.	Silicone tube (2X0.5mm / 4X1mm / 6X2mm / 7X1.5mm / 10X2mm) 	<ul style="list-style-type: none"> Data sheet silicone hose 60 Shore 	1.7.3 Specification packaging material
5.	LDPE bubble wrap 	<ul style="list-style-type: none"> Data sheet Lupo 	1.7.3 Specification packaging material
6.	PUR flexible foam 	<ul style="list-style-type: none"> PUR flexible foam MA 2240 	1.7.3 Specification packaging material

Due to the small size and low weight, we are not aware of any negative feedback regarding transport damage. We have implemented packaging instructions as part of our QM system and validated the packaging/transport.

1.2 Secondary packaging(s)

LDPE flat bags, cases or wooden crates are used as secondary packaging. They therefore provide additional protection. The products are also adequately protected from damage using cardboard packaging, filling paper, bubble wrap and packaging chips.

No.	Description	Data sheet	Evidence / location
1.	LD/PE film (bag) 	<ul style="list-style-type: none"> Data sheet LDPE flat bags 	1.7.3 Specification packaging material
2.	Transparent cases 	No evidence available as not critical. The case and insert have no direct contact with the products.	n/a

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3.	Filling paper  	No evidence available as not critical. The paper has no direct contact with the products.	n/a
4.	LDPE bubble wrap 	<ul style="list-style-type: none">• Data sheet Lupo	1.7.3 Specification packaging material
5.	Packaging chips 	No evidence available as not critical. Packaging chips have no direct contact with the products.	n/a