

Product specification


Device group: Protection shield

Doc-id: TF19_SPEC

Revision: 01

Pgs: 1 (2)

Product specification

Trade name(s)	FenderWedge® FenderWedge® Prep			
Sample illustration				
Intended use	<p>Interdental shield and wedge used to protect and separate during dental preparation.</p> <p>A steel shield and plastic wedge integrated into one-piece device to be placed interproximal in the oral cavity during preparation. The purpose of the shield is to prevent adjacent tooth from bur damage. The purpose of the wedge is to protect gingival papillae and separate the teeth simplifying the application of a matrix.</p> <p>Indications:</p> <ul style="list-style-type: none"> -Class II and class III preparations -Veneers and crown preparations -Model Prep is for larger preparations 			
Claims/Features	<ul style="list-style-type: none"> - Prevent bur damages - Protect gingiva papillae - Biocompatible material 			
Models/dimensions	Model X-small Small Medium Large Prep	Colour purple orange green yellow grey	Thickness plate 0.08mm 0.08mm 0.08mm 0.08mm 0.08mm	Thickness & Height Wedge 1.4 x 1.8mm 1.7 x 2.0mm 2.0 x 2.5mm 2.3 x 2.5mm -
Packages	<p>Assortment: 36 of each model x-small, small, medium, large. Each model is packed in a plastic box. Cardboard outer package.</p> <p>Each model available as: -36 pcs packed in a plastic box. -100 pcs packed in a cardboard (value package).</p> <p>Assortment intro-kit: FenderWedge: 3 pcs of each model x-small and small. 1 pc of each model medium and large.</p>			

Technical File TF19

DIRECTA

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	FenderMate: 8 pcs of each model left narrow and right narrow. 2 pcs of each model left regular and right regular
Single use/re-usable	Single use.
Material	Plate: stainless steel Wedge: polypropylene
Shelf-life	The device has no shelf-life restriction.
Storing and transport conditions	The device has no specified storage or transport conditions.
Supply	Supplied non-sterile.
Hazards likely with re-use of single use medical devices	Cross-contamination/function The device cannot be properly reprocessed due to its design and not used as per intended use, as the device has been damaged during use.

Revision history

Revision	Date	Completed by	Approved by	Remark
01	2021-05-18	Agneta Bengtsson, RA 	Sandra Peioponen, Product Manager 	Initial document