



Safety Data Sheet (SDS)

Amtouch Aligner Chewies

SECTION 1- PRODUCT IDENTIFICATION AND EMERGENCY INFORMATION

Product Name:	ALIGNER CHEWIE
Catalog Numbers:	AMAC-PU, AMAC-WH
Product Class:	ALIGNER CHEWIE
24-Hour Emergency Phone Number:	1-800-222-1222

SECTION 2-HAZARDOUS COMPONENTS-N/A

SECTION 3-INTENDED USE

Intended Use:	The Aligner Chewie is designed to aid in fitting aligners or retainers to patient teeth by chewing for short periods of time while placing the tray on the teeth under normal oral body temperature ranges
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SECTION 4-INDICATIONS FOR USE

Indications:	Suitable for patients wearing thermoformed aligners or retainers.
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SECTION 5-PERFORMANCE CHARACTERISTICS AND CLINICAL BENEFITS

Material:	Made of a soft, chewable material to help patients properly seat their aligner or retainer.
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SECTION 6-WARNINGS

Single Patient Use:	For single patient use only. Do not reuse on another person
Excessive Pressure:	Using excessive pressure to seat the aligner or retainer may cause damage

SECTION 7-PRECAUTIONS

Momentary Use:	For momentary use for seating aligner or retainer only
Single Aligner/Retainer	Seat only one aligner or retainer at a time. Attempting to seat two at once may result in damage.
Infection Risk:	Do not reuse the product on another person. Risks of reuse include infection and cross-contamination
Reporting:	Report serious incidents related to the device to

	your healthcare professional or the device manufacturer
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SECTION 8-ADVERSE REACTIONS

Adverse Reactions:	None known
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SECTION 9-STEP-BY-STEP INSTRUCTIONS

Placement:	Place the aligner or retainer over the teeth by hand and apply slight pressure until it is seated most of the way
Insert Chewie:	Insert the Aligner Chewie into your mouth and position it between the upper and lower arches.
Bite Gently:	Gently bite down on the Aligner Chewie and work the aligner or retainer into place until fully seated

SECTION 10-SAFE DISPOSAL

Disposal:	Dispose of the device in regular household trash, similar to a used toothbrush or dental floss.
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SECTION 11-WARRANTY AND LIMITED REMEDY

Warranty::	The manufacturer warrants that this product is free from defects in materials and manufacture.
Limited Remedy::	The manufacturer's sole obligation and customer's sole remedy in the event of a claimed defect shall be limited to replacement merchandise or refund of the purchase price
Disclaimer: :	All implied warranties, including merchantability or fitness for any particular purpose, are disclaimed.

SECTION 12-LIMITATION OF LIABILITY

Liability::	Except where prohibited by law, the manufacturer will not be liable for any loss or damages arising from this product, whether direct, indirect, special, incidental, or consequential.
Personal Injury:	This limitation does not apply to third-party personal injury claims

SECTION13: OTHER INFORMATION

Other Information	This product is intended for oral hygiene only and should not be used for other purposes.
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