



F 2726-08

**Standard specification for fixation devices for
tracheal tubes and other airway devices**



Contents	Page
FOREWORD	I
INTRODUCTION	II
1. SCOPE	3
2. NORMATIVE REFERENCES	3
3. TERMS AND DEFINITIONS	4
4. *GENERAL REQUIREMENTS	5
5. *REQUIREMENTS	5
5.2 SIZE DESIGNATION	6
5.3 MATERIALS	6
5.4 PATIENT ATTACHMENT MECHANISM	6
5.5 TUBE LOCKING MECHANISM	7
5.6 SECURITY OF ATTACHMENT	7
5.7 MAXIMUM INSTRUMENT SIZE	8
6. REQUIREMENTS FOR FIXATION DEVICES SUPPLIED STERILE	8
7. CLEANING AND DISINFECTION OR STERILIZATION	9
8. MARKINGS	9
9. ACCOMPANYING DOCUMENTS	10
ANNEX A (INFORMATIVE) RATIONALE	11
ANNEX B (INFORMATIVE) GUIDELINES FOR EVALUATING AND DOCUMENTING THE CLINICAL PERFORMANCE OF FIXATION DEVICES IN HUMAN SUBJECTS	14
ANNEX C (NORMATIVE) TEST FOR SECURITY OF ATTACHMENT	16
ANNEX D (NORMATIVE) TEST METHOD TO DETERMINE THE CHANGE IN PRESSURE DROP CAUSED BY THE TUBE LOCKING MECHANISM	18
ANNEX E (INFORMATIVE) HAZARD IDENTIFICATION FOR RISK ASSESSMENT	20
ANNEX F (INFORMATIVE) GUIDANCE ON MATERIALS AND DESIGN	22
ANNEX G (INFORMATIVE) BIBLIOGRAPHY	23



Foreword

This ASTM standard was developed as an American National Standard by ASTM Committee F29, *Anesthesia and Respiratory Equipment*, Subcommittee F29.12, *Airways*, Task Group 29.12.08, *Tracheal Tube Fixation Devices*, in the format of an ISO standard to serve as a guide for future work as a new ISO Standard.

This is the first edition of this standard.